

Written MDR reports for the above listed incidents should be submitted within 15 working days of receipt of this letter. If these reports cannot be submitted within that time period, you should provide this office with a response which indicates when the reports will be submitted. The MDR reports should reference this Warning Letter and be directed to:

Mrs. Victoria A. Schmid
Division of Surveillance Systems (HFZ-533)
Office of Surveillance and Biometrics
Food and Drug Administration
1350 Piccard Drive
Rockville, Maryland 20850

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the regulations, as well as other requirements of the Act. Continued distribution of violative devices may result in regulatory action without further notice. These actions include, but are not limited to seizure, injunction, and/or civil penalties.

Federal agencies are advised of the issuance of all warning letters regarding medical devices so that they may take this information into account when considering the award of contracts.

You should notify this office in writing within 15 working days of receipt of this letter, of any additional steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the correction will be completed.

Your reply should be sent to the Food and Drug Administration, Denver District Office, Attention: Regina A. Barrell, Compliance Officer. Please provide Ms. Barrell with a copy of each MDR report sent to Ms. Victoria Schmid.

Sincerely,


Gary C. Dean
District Director

PURGED